

Reagent kit for quantitative estimation of α -Amylase in Serum or Plasma or Urine.

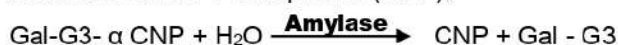
DIAGNOSTICS SIGNIFICATION:

α -Amylase catalyses the hydrolysis of 1-4 glucoside linkages of starch and other related polysaccharides to produce maltose and other oligosaccharides. The enzyme is a relatively small molecule which is rapidly cleared by the kidneys and excreted in the urine.

Amylase is mostly measured for the diagnosis of acute pancreatitis where in serum levels are found to be elevated. In acute pancreatitis α -Amylase starts rising approximately four hours after the onset of pain, reaches peak at 24 hours and remains elevated for 3 to 7 days. High levels of amylase are also associated with other disorders, like biliary tract diseases, severe glomerular dysfunction and salivary gland disorders and rapture ectopic pregnancy

PRINCIPLE:

Amylase uses a chromogenic substrate Gal-G3- α CNP which, by the reaction of α - Amylase breaks down to release 2-Chloro-4-Nitrophenol (CNP).



The release of 2-Chloro-4-Nitrophenol (CNP) is measured at 405 nm and is proportional to α - Amylase activity.

SPECIMEN COLLECTION:

Serum or heparinised plasma is suitable. EDTA, Oxalate, or Citrate inhibit the amylase activity, hence cannot be used. Amylase activities in serum samples remain stable for 20 days at 2-8^oC.

KIT PRESENTATION:

Pack Size	2 X 5 ml	10 Test	2 X 10 ml	2 X 25 ml
Amylase Reagent	2 X 5 ml	10 X 1 ml	2 X 10 ml	2 X 25 ml

REAGENT STORAGE AND STABILITY:

α -Amylase Reagents are stable until the expiry date stated on the label when stored at 2-8^oC.

LIMITATIONS:

Avoid contaminants like Saliva, Cough, Sneeze would affect the Reagent, since these contain many units of Amylase which might affect the reagent for color development and its value too.

ASSAY PARAMETERS:

Reaction	: Kinetic	Sample Volume	: 20 μ l
Wavelength	: 405 nm	Reagent Volume	: 1.0 ml
Flow Cell Temp.	: 37 ^o C	Factor	: 3806
Initial Delay	: 60 Sec	Reaction Slop	: Increasing
Interval Time	: 30 Sec	Zero Setting	: Dist. Water
Read Time	: 90 Sec	Linearity	: 2000
No. of Reading	: 03	Unit	: IU/L

PROCEDURE:

Addition Sequence	Test
Amylase Reagent	1.00 ml
Sample (Test)	20 μ l

Mix & aspirate immediately and read **first** absorbance of test exactly at 60 seconds and then, **second, third** and **fourth** at an interval of 30 seconds at 405 nm. Determine the mean change in absorbance per minute. ($\Delta A/\text{min}$) and calculate the test results.

CALCULATION:

Serum Amylase Activity (IU/L) = $\Delta A/\text{min}$ X Factor

NORMAL VALUES:

Serum/ Plasma : 35 – 98 IU/L at 37^oC
Urine : up to 490 IU/L at 37^oC

LINEARITY:

This method is linear up to **2000 IU/L**. For values above 2000 IU/L, dilute the sample suitably with 0.9 % saline, and repeat the assay. Apply correction due to dilution to arrive at a final result.

REFERENCE:

1. JF Zliva and PR, Pannall, "Plasma Enzymes in Diagnosis" in Clinical Chemistry in Diagnosis and Treatment, Lloyd-Luke London 1979 : Chapter XV.
2. Junge, w., et al, clin. biochem. 22,109 (1989).

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Expiry Date



In-Vitro Diagnostics Use



Storage



Mfg. Date



Batch Number



Catalogue Number



See Package Insert